UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,986	08/29/2006	Michio Yamamura	0020-5507PUS1	2444

2292 7590 10/10/2007
BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

NOTIFICATION DATE	DELIVERY MODE
10/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,986	YAMAMURA ET AL.	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 29, and October 27, 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/27/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

Applicant is respectfully requested to amend the abstract because the present Abstract is not in US PTO format.

The instant disclosure fails to include "Cross-References to Related Applications." See 37 C.F.R. §1.78 and MPEP at §201.11. Applicant is respectfully requested to include the requested information as the first paragraph of the disclosure.

No claims have been cancelled, claims **1-7 and 9** have been amended, the disclosure has not been amended, and no new claims have been added as per the preliminary amendments filed August 29, 2006 and October 27, 2006. One Information Disclosure Statement (1 IDS) filed October 27, 2006 has been received with all non-US Patent references and made of record.

Claims **1-9** remain in the case.

Claims **1-6 and 9** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for administration of ribose or ribose plus potassium magnesium aspartate to improve mammalian physical performance when under stress as well as memory performance, does not reasonably provide enablement for the treatment of the vast array of other disease conditions encompassed by terms including "indefinite complaint," "decline in thinking power," "impaired sight," "mental overstrain," and "mental disorder." The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The claims are directed to the treatment of depression-like symptoms," a term that is defined so broadly that the instant claims may be read to include the treatment of mental disorder including "schizophrenia," "manic depression," "low intelligence," and "epilepsy." The breadth of the claims is clearly excessive in view of the limited number of specific exemplifications.

B. The nature of the invention: This subject is dealt with by the previous paragraph.

C. The state of the prior art: The administration of ribose to treat various conditions in mammals or to promote improvements in the physical conditions of mammals is well known in the art as clearly and repeatedly established by the prior art of record.

D. The level of one of ordinary skill: Based on the extensive disclosures found in the prior art, one of ordinary skill would be expected to the size of effective dosages of ribose and to know how to administer an effective dose of ribose to a mammalian host.

E. The level of predictability in the art: The predictability in this are is a function of what physiological results is desired and what is known about obtaining this kind of result in the prior art. At present the prior art of record has very little disclosure of the effect of ribose in mental functions per se, but does suggest that ribose administration does improve ATP generation and may be administered in a strength increasing regimen,

F. The amount of direction provided by the applicants including working examples: The instant disclosure include 6 working examples and one comparative example wherein lower mammals directed to measuring the effects of ribose in various test regimens wherein lower mammals are stressed by the requirement for physical exertion (e.g. swimming when weighted) and wherein humans are tested for memory acuity with and without ribose

supplementation. However, there is no data showing effective treatment of human hosts established to be suffering from depression.

G. The existence of working examples: This subject is dealt with by the previous paragraph.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because the terminology provided in the claims to define the conditions to be treated far exceeds a reasonable interpretation of what conditions are actually effective treated and therefore enabled by the test regimens disclosed.

Claims **1-3 and 7-8** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims **1 and 2** the definition of "depression-like symptoms" in claim **2** extends into subject matter usually associated with the medical definition of "depression (See **Venes et al.**, PTO-892 ref. **R**). Therefore, while applicants are free to be their own lexicographer, definitions that extend to areas not usually associated with a well-accepted definition of "depression" and the symptoms thereof, render the instant claims lacking in proper definition. See *In re Hill,* 161 F.2d 367, 73 USPQ 482 (CCPA 1947).

In claim **2** at line 4, the term "such as" is open-ended terminology and therefore renders the instant claims indefinite for lack of well-defined metes and bounds. Deletion of the term is respectfully requested.

In claim **3** at line 3 the term "mental overstrain or mental disorder" is lacking in proper antecedent basis and also extend well beyond the definition of the term "depression" or the symptoms normally associated therewith. While the term -- further comprising -- if added to this claim would permit extension of the scope of claims **1 and 2**, this change would not effectively address other problems noted above.

In claims **7 and 8** applicant appears to be claiming -- pharmaceutical compositions --. -- Pharmaceutical composition -- claims - may be presented as follows: -- A pharmaceutical composition comprising {active ingredient(s)} in combination with a pharmaceutically

acceptable carrier.--. Applicant is respectfully requested to amend the instant claims to acknowledge by amendment that a "composition" must include at least two different chemical substances (e.g. claim **8** is presently incomplete because no carrier or excipient has been included in the claim), and preferable to include appropriate carriers in both of the noted claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

"A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent."

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States."

(e) the invention was described in

(1) an application for patent described under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application filed under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)."

(f) he did not himself invent the subject matter sought to be patented."

Claims **7-8** are rejected under 35 U.S.C. §102(**a**) and (**e**)) as being anticipated by **Vazquez et al. '027** (PTO-892 ref. **E**).

Applicant is directed to the instant reference at column 1, lines 48-55, thge paragraph bridging columns 1 and 2 ending at lines 1-2 of column 2, and at column 2 at lines 46-50 wherein the instant claimed compositions have been clearly anticipated.

Claims **1-6 and 9** are rejected under 35 U.S.C. §102(**a**) and (**e**)) as being anticipated by **Vazquez et al. '027** (PTO-892 ref. **E**).

Applicant is referred to column 6 of the instant reference wherein the administration of compositions comprising ribose, carnitine and a magnesium compound to a human host to

improve stamina. This claim anticipates the instant claimed subject matter because increases in stamina may be defined as having the effect of improving a host at baseline (not suffering from depression) or as having the effect of improving a host suffering from depression (suffering from depression) by raising performance to, or to above, baseline. Therefore, the instant claims are anticipated by the claims of the **'027** reference, particularly the **'027** reference at claim ***6***.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **1-9** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Vazquez et al. '027** (PTO-892 ref. **E**) in view of **Palazzi et al. '311** (PTO-1449 ref. **A2**).

The instant claims are directed to compositions containing ribose or a mixture of ribose, carnitine and a magnesium salt of aspartic acid or only a composition containing ribose as the active ingredient.

Vazquez et al. '027 discloses at column 1, lines 48-55, the paragraph bridging columns 1 and 2 ending at lines 1-2 of column 2, and at column 2 at lines 46-50 compositions wherein ribose alone or ribose in combination with other ingredients including carnitine and a magnesium compound have been disclosed. The reference also claims the administration of the above-defined compositions to improve mammalian stamina.

Vazquez et al. '027 does not expressly disclose any specific compound wherein a magnesium ion is present.

Palazzi et al. '311 discloses at page 7, in claims ***2 and 5*** that the compounds "magnesium aspartate" and "potassium aspartate" may be present in compositions containing ribose.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to selected a magnesium and potassium containing salt of aspartic acid in view of the teachings of the **Palazzi et al. '311** reference because both instant cited references

are directed to ribose containing compositions wherein aspartate salts. It would also have been obvious to the ordinary practitioner seeking to optimize the prior art to amend the method of **Vazquez et al. '027** by incorporating potassium and magnesium salts of aspartic acid as taught by the **Palazzi et al. '311** reference.

One having ordinary skill in the art would have been motivated to combine these references because both cited references are, according to their titles, directed to improving adenine nucleotide content of muscles and improving muscle performance by the administration of ribose and magnesium-ion-containing compositions to a host in need thereof. These effects are consistent with improving the performance of a depressed host, particularly if said depression is manifested by reduced mental performance.

Therefore, the instant claimed methods of treatment, and ribose/carnitine/magnesium salt-containing compositions to be administered therefore, would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

Applicant is also respectfully requested to note that the above rejection is further supported by the well established legal principle that claiming an unpatentable compound (or sum of compounds) in combination with a carrier does not render the combination patentable if it would be obvious in the prior art to utilize a carrier with the compound: see *Ex parte Billman.*, (POBA 1946), 71 USPQ 253; *In re Lerner* , (CCPA 1971) 438 F2d 1008; 169 USPQ 51; and *In re Rosicky* , (CCPA 1960) 276 F 2d 656, 125 USPQ 341. This addendum particularly applies to instant claims **7 and 8**.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published

in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

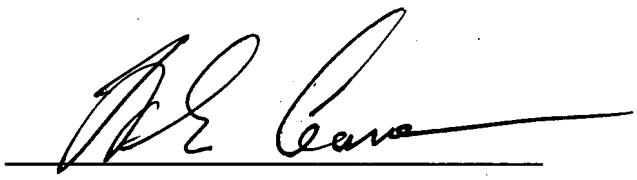
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
09/30/2007



L. E. Crane, Ph.D., Esq.
Primary Patent Examiner
Technology Center 1600